
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Sandra M. Maclean	
Appln. No.:	10/664,236	
Filing Date:	September 17, 2003	Examiner: Hill, Laura C.
Title:	MISCARRIAGE CARE PACKAGE	Group Art Unit: 3761

**DECLARATION UNDER 37 C.F.R. § 1.132 TO OVERCOME
CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)**

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I, Dr. Laura Dean, hereby declare that:

1. I am the immediate past vice chair of the American College of Obstetrics and Gynecology Minnesota Section. I have served as Junior Fellow Chair of ACOG District VI (IL, IA, MB, MN, NE, ND, SK, SD, and WI). I am a member of the board of directors for the Ramsey County Medical Society, am a member of the American Medical Association, and am a member of the Minnesota Medical Association. I am in group practice at the Stillwater Medical Group, PA, in Stillwater, MN. I received my bachelor's degree from the College of Saint Thomas in St. Paul, MN, received my medical degree from the Mayo Medical School in Rochester, MN, and completed my residency at the University of Minnesota in Minneapolis, MN.

2. A fetus does not constitute bodily waste, but rather, is properly characterized as human tissue. Furthermore, the collection and containment of human tissue, and specifically fetal remains, should not be equated with nor handled in the same manner as feces, vomit, or other bodily waste. Accordingly, it is my opinion, that it would not be obvious to modify or combine inventions directed to collection and containment of bodily waste to achieve the miscarriage care package of the present invention.

3. The waste cleanup kit of U.S. Patent No. 4,917,238 ("Schumacher") is explicitly described as a single-use item which may be used and then readily disposed. *Schumacher*, col. 1, ll. 37-

40, col. 2, ll. 61-63. In contrast, the miscarriage care package, and specifically the specimen pan, as described in the present invention, is designed for sustained, multiple use. Such a design is imperative because of the nature of a miscarriage. During the miscarriage process, a fetus and fetal tissue are expelled unpredictably over the course of one or more days, thereby necessitating multiple uses of collection items. For this reason, it is my opinion that it would not be obvious to modify the waste cleanup kit of Schumacher to include a durable specimen pan capable of use in multiple episodes that would conclude with the expulsion of the fetus and/or fetal tissue. To the contrary, it is my opinion that the objective of Schumacher, to provide a single-use cleanup kit, creates a disincentive to modify the kit in such a manner.

4. The container of Schumacher is incapable of accommodating a size of fetus which may be expelled during a miscarriage. The average fetal size and weight at 20 weeks, as defined by the U.S. obstetrical standards, is 25.6 cm and 300 grams. Schumacher describes a container sized to accommodate 6 to 7 fluid ounces. *Schumacher*, col. 3, ll. 15-16. Accordingly, the container of Schumacher is incapable of performing the intended use of the container of the present invention.

5. The invention of U.S. Patent No. 6,434,762 ("Gordon") is directed to an apparatus for collection and containment of human feces. Feces exit the body via the anus. In contrast, human tissue from a miscarriage leaves the female body through the lower part of the cervix and vagina. Thus, the stool collecting apparatus of Gordon provides collection at a different anatomical site that does not coincide with the site for collection of human tissue from a miscarriage. Further, forward positioning of the center strip 12 of Gordon on the toilet seat to align with the female vagina and cervix would not be sufficient to enable use for receiving human tissue from a miscarriage because the opening 18 and stool receptacle 14 of Gordon are insufficient to effectively capture and contain fetal tissue. Accordingly, it is my opinion, that the invention of Gordon does not disclose nor would it make obvious a specimen pan for receiving human tissue.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issued thereon.

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